

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Re:

Title:

BISARYL DERIVATIVES HAVING FSH

MODULATORY ACTIVITY

Serial Number

10/623,640

Applicant:

Guo et al.

Agent's File Reference:

1073.071

<u>Petition under 37 CFR §5.25 for a Retroactive License under 35 U.S.C.</u> <u>184</u>

Dear Sirs:

Enclosed please find the materials necessary for a § 5.25 Petition for a Retroactive License under 35 U.S.C. 184. Applicant respectfully requests that you review the materials and grant retroactive foreign filing licenses for the subject matter of two European applications titled "Bisaryl Derivatives"

The following information is provided for your review:

- (1) The subject matter of the patent application material contained in US serial number 10/623,640 "Bisaryl Derivatives Having FSH Modulatory Activity" was developed through a joint venture between Pharmacopeia, Inc.(Cranbury, NJ, United States), and N.V. Organon/ Akzo Nobel N.V. (The Netherlands). Pharmacopeia, Inc. developed a library of compounds and tested the initial series of compounds for FSH activity in the United States.
- (2) The subject matter was initially filed in a first application for a European Patent by N.V. Organon/Akzo Nobel on December 3, 1999. This application, EP 99 204109.5, was withdrawn in November 2000.
- (3) The material was filed a second time in a second application for a European Patent by N.V. Organon/Akzo Nobel on January 19, 2001. Pharmacopeia was named as co-applicant. The second application, EP 01 200194.7, was deemed withdrawn on July 12, 2001.
- (4) Unlicensed patent application material disclosing at least some portion of the subject matter of US 10/623,640 was thus twice filed for a European Patent by N.V. Organon/Akzo Nobel.
- (5) On December 19, 2001 N.V. Organon/ Akzo Nobel assigned all remaining interest in EP 01 200194.7 to Pharmacopeia, Inc.
- (6) On November 18, 2002, Pharmacopeia filed a PCT application (PCT/US02/03777) claiming the priority of EP 01 200194.7.

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(7) On July 21, 2003, Pharmacopeia, Inc. filed a US patent application (10/623,640) entering the PCT into the national phase in the United States. It was at this point that the question of a license under 35 USC 184 first occurred to the applicants. This petition is therefore diligently filed.

Docket No.: 1073.071

- (8) Because both earlier European filings were undertaken by European agents under the direction of a European applicant, it did not occur to either party that a possibility might exist that a US license under 35 U.S.C. 184 might have been required. Upon discovery of the error, applicants now seek a retroactive license under 35 U.S.C. 184. Assuming the filings of the applications for a European patent without a license were in error, the error was without deceptive intent.
- (8) A verified statement (declaration) from Dr. Marijke Hogenbirk, N.V. Organon Patent Department, is attached containing:
 - (i) an averment that the subject matter in question was not under a secrecy order at the time it was filed abroad;
 - (ii) an explanation of why the material was filed abroad through error and without deceptive intent without the required license under § 5.11 first having been obtained.
- (9) The subject matter in question is not currently under a secrecy order. In fact, both the pending US application (10/623,640) and the PCT on which it is based (PCT/US02/03777) have been granted foreign filing licenses.
- (10) The required fee according to 37 CFR § 1.17(h) is enclosed.

Applicants respectfully request that the USPTO consider the filing of this petition as a sufficient showing that the foreign filing license has been diligently sought after discovery of the proscribed foreign filing. If there are any further materials that would facilitate review of this request, please contact applicants' undersigned representative.

Sincerely,

HESLINAROTHENBERG FARLEY & MESITI P.C.

Philip E. Hansen

Agent for Applicants

U.S. Reg. No.: 32,700

PEH/lab **Enclosures**



File No.: 1073.071

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Pharmacopeia, Inc. et al.

Title:

Bisaryl Derivatives Having FSH Modulatory Activity

Serial Number

10/623,640

Applicant:

Guo et al.

Agent's File Reference:

1073.071

Declaration of Dr. Marijke Hogenbirk N.V. Organon, Patent Department Pharma

The undersigned, hereby declares as follows:

- 1. The subject matter of the patent application material contained in "Bisaryl Derivatives Having FSH Modulatory Activity" was developed through a joint venture between Pharmacopeia, Inc.(Cranbury, NJ, United States), and N.V. Organon/ Akzo Nobel N.V. (The Netherlands). Pharmacopeia, Inc. developed and tested a library of compounds in the United States which were supplied to N.V. Organon in The Netherlands for further study.
- 2. I was responsible for the preparation and filing of European patent applications relating to "Bisaryl Derivatives Having FSH Modulatory Activity". Because the subject matter derived from work done in part in the Netherlands, and because Organon/ Akzo Nobel N.V. is a European company, and because the applications were to be filed in the European Patent Office, the question of obtaining a license under United States law never arose and was never considered.
- 3. The subject matter of the patent application material contained in "Bisaryl Derivatives Having FSH Modulatory Activity" was not under a secrecy order at the time it was filed in an application for a European patent.
- 4. On December 3, 1999, N.V. Organon/ Akzo Nobel N.V. prepared and filed an application (EP 99 204109.5) for a European patent. A copy is enclosed.
- 5. On January 12, 2000 Pharmacopeia, Inc. was added as a second applicant for EP 99 204109.5.
- 6. In November 2000, EP 99 204109.5 was withdrawn.

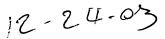
- 7. On January 19, 2001, an application for a European patent covering substantially the same subject matter was re-filed by N.V. Organon/ Akzo Nobel N.V. Pharmacopeia, Inc. was included as an applicant on this application (EP 01 200194.7). A copy is enclosed.
- 8. On July 12, 2001 EP 01 200194.7 was deemed to be withdrawn.
- 9. On December 19, 2001 N.V. Organon/ Akzo Nobel assigned all remaining interest in the European priority application EP 01 200194.7 to Pharmacopeia, Inc.

I further declare that all statements of the foregoing declaration made of my own knowledge are true and that those made upon information and belief are believed true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Signed by me this 4 day of December, 2003. OSS, the Netherlands

Marijke Hogenbirk







CERTIFICATE OF MAILING BY "EXPRESS MAIL"

Applicant: Guo et al.

Title: BISARYL DERIVATIVES HAVING FSH MODULATORY ACTIVITY

Attorney Docket No.: 1073.071

"EXPRESS MAIL" Mailing Label No.: EV 244384830 US

Date of Deposit: December 23, 2003

Enclosed are:

* Express Mail Certificate - Label No.: EV 244384830 US

* One (1) Acknowledgment Postcard

* Check for \$130.00 (Petition to the Commissioner Fee)

* Petition under 37 CFR § 5.25 for a Retroactive License under 35 U.S.C. 184 (2 pages) (w/2/references)

* Utility Patent Application (186 pages)

* Executed Declaration of Dr. Marijke Hogenbirk N.V. Organon, Patent Department Pharma (2 pages)

37 CFR 1.10 Certification

I hereby certify that this paper and the indicated enclosures are being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and addressed to:

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Christine Weber

(Typed or printed name of person mailing paper or fee)

(Signature of person mailing paper or fee)